Protecting our Kids: What is causing the current shortage in childhood vaccines?

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Introduction

Good morning Mr. Chairman and members of the Committee.

I am Dr. Walter Orenstein, Director of the National Immunization Program at the Centers for Disease Control and Prevention (CDC). The Committee requested that CDC testify about the current childhood vaccine shortage. There are currently supply problems with five vaccines that provide protection against eight of the eleven vaccine-preventable childhood diseases: Diphtheria, Tetanus, Pertussis (DTaP and Td vaccine), Pneumococcal infection (PCV-7 vaccine), Measles, Mumps, Rubella (MMR vaccine), and Varicella. Three of the four major manufacturers of childhood vaccines have recently had trouble producing adequate supplies of at least one of their products.

The current childhood vaccine shortages are unique and unprecedented. Several unusual and unanticipated factors have converged to create this situation. Health care providers and parents have been justifiably frustrated and worried by the shortages. The Department of Health and Human Services takes these concerns very seriously, and CDC is monitoring the situation in a variety of ways.

CDC was asked specifically to discuss the causes and extent of the shortages, their expected duration and impact, and CDC=s role in maintaining the supply of childhood vaccines. We appreciate the opportunity to update you today on the current vaccine shortages and the steps CDC is taking to address the situation. Before I address these issues, I would like to point out some good news - current information from manufacturers indicates that many of these shortages will be over before the end of the summer, and most will be resolved by the end of this year.

Background

Immunization is considered one of ten great public health achievements of the 20th Century. Indeed, vaccine-preventable disease levels are currently at or near all-time lows, and childhood immunization coverage levels have been at all-time high levels during the last several years. This success is in no small part due to the innovative and highly effective role of the private sector (often in partnership with innovators in academia and government) in vaccine development and production in the United States and abroad, and the widespread use of licensed vaccines. Many of the childhood vaccines routinely recommended in the U.S. and elsewhere in the world, such as Polio, Measles, Mumps, and Rubella (MMR), *Haemophilus influenzae* type b (Hib), Hepatitis B, and Pneumococcal conjugate vaccines, were first brought to the market by private companies. Furthermore, competition among private pharmaceutical companies has resulted in substantial innovation, such as new and safer vaccines, which saves lives and prevents disease and disability.

For more than 15 years, our nation's children have had steady access to vaccines. The minor disruptions in production that have occasionally occurred in the past have been resolved through mobilizing vaccine from national stockpiles, and through the Food and Drug Administration (FDA), CDC, and partners working with manufacturers to increase vaccine supplies.

The Causes and Extent of the Current Vaccine Shortages

Causes: The causes of the current childhood vaccine shortage are multi-factorial and complex. We cannot point to any single reason for the shortage, but rather must look at specific issues affecting shortages of specific vaccines. There is no apparent single characteristic of any of these vaccines at the root of the shortage. Vaccines included in the shortage are both new, such as Pneumococcal Conjugate vaccine (PCV-7), and long-standing, such as Measles, Mumps and Rubella vaccine (MMR).

In general, marketplace and economic factors play an important role in vaccine supply. The fact that there are relatively few manufacturers producing vaccine means that any disruption in one manufacturer's production has a major impact on the vaccine supply. This problem is particularly acute when there is only one manufacturer for a vaccine, which is the case for three of the vaccines that have been in short supply. Vaccines, in general, may not compete well financially with other pharmaceutical products within a company, which may lead to business decisions to decrease or stop vaccine production. Economic issues are clearly critical to the long-term viability of the vaccine industry. However, such issues may not have been the immediate cause of many of our current problems.

We do not have access to data on production and development costs or profits, but we do have access to price data for the public

sector and catalog prices for the private sector. Shortages are occurring with vaccines that range widely in cost (Figure 1), an indication that low prices for some of the vaccines may not be the main factor in the shortages. Four of the five vaccines for which there are supply problems (PCV-7, Varicella, MMR, and DTaP) had relatively high prices, ranging from $11.75 per dose to $45.99 per dose on the Federal contract. In contrast, the three vaccines without supply problems range in price from $7.63 to $9.43 per dose. If economics were the single most critical driving factor in this situation, we would have expected to see shortages of the lower priced, and presumably less profitable, vaccines.

Some of the factors that are contributing to the current shortage include manufacturers' production capacity, regulatory compliance issues, manufacturers' business decisions to stop producing certain vaccines, and decreases in production yields caused by changing to single-dose vials to remove the preservative thimerosal from one of the vaccines.

In some cases, manufacturers of vaccines currently in shortage recently implemented changes in their production practices that contributed to decreased vaccine output, usually of a temporary nature. Some of these changes were related to manufacturing problems and others related to efforts to comply with current Good Manufacturing Practices (cGMP). FDA is addressing the cGMP issues in their testimony in more detail.

Unanticipated and abrupt business decisions by some manufacturers to leave the market have also had an impact on the vaccine supply, particularly in the case of vaccines containing tetanus and diphtheria toxoids (Td and DTaP). For example, when one major producer stopped making Td, the remaining company was unprepared to immediately fulfill the resulting supply needs. In the case of DTaP vaccine, two of the four manufacturers abruptly discontinued production. Further, one of the two remaining manufacturers made changes in production as part of an effort to remove thimerosal, a mercury-containing preservative, from its DTaP vaccine. While there is presently no scientific evidence showing any causal association between thimerosal and adverse events, these changes were made in response to Public Health Service (PHS), American Academy of Pediatrics (AAP) and American Academy of Family Physicians (AAFP) precautionary recommendations, intended to reduce overall exposures of infants to mercury in a setting where other exposures to mercury (e.g. food, environmental) were more difficult to control. The removal of thimerosal as a preservative for these pediatric vaccines was accomplished through switching from multi-dose to single dose packaging. Packaging vaccine in single dose vials requires a greater volume of vaccine per dose compared to multi-dose vials, to ensure that a full dose can be drawn from the vial, resulting in fewer doses available for distribution.

Extent: While the shortage is considered national in scope, the extent varies by vaccine, with some shortages being more widespread than others. Vaccine manufacturers with whom CDC

has contracts routinely submit quarterly Biologic Surveillance Reports to CDC showing total numbers of doses of vaccine distributed nationally, through both public and private purchase. When pre-shortage and current distribution data are compared, the vaccines most significantly affected appear to be Td and Pneumococcal vaccine, which both show a 40% decrease in doses distributed nationally. There was a less dramatic decrease in doses of varicella vaccine distributed; between 26% and 29%, depending on the periods compared. The MMR shortage was alleviated in part by drawing from an existing CDC stockpile, but there still has been a 15% reduction in doses distributed.

Shortages have also varied by location and health care provider. Some health departments, clinics, and physicians have adequate supplies of vaccines, while others are experiencing vaccine shortages or delays in vaccine delivery.

The Duration and Impact of the Current Vaccine Shortages

Duration: Some vaccines have been in short supply longer than others. Shortages of each vaccine did not start at the same time, and supply has varied month to month. How long the shortage is expected to continue also varies by vaccine, but several shortages are likely to be improving or resolved in the next 2 to 4 months. Predicting the duration of the shortages is dependent on manufacturer projections. These projections are continuously adjusted as the situation evolves.

In general, manufacturer projections indicate that the situation is rapidly improving. Based on information just received from the manufacturer, we anticipate returning to the routine schedule for Td around the end of this month. CDC will shortly make an announcement about this. The FDA licensure on May 14, 2002 of a new DTaP vaccine brought additional DTaP vaccine to the market. Since approval on May 14th, FDA has released five lots of the vaccine, which could alleviate the DTaP shortage more rapidly. Based on information just received from one of the manufacturers, we anticipate that the DTaP shortage will be resolved soon. Also, according to the manufacturer, the supply of MMR and Varicella vaccines should be improving in June, and the shortage is expected to be resolved by the end of July and August, respectively. Our most significant and enduring problem appears to be with pneumococcal conjugate vaccine; according to manufacturer projections, pneumococcal conjugate vaccine will be in short supply through this fall and probably into 2003.

Impact: The impact of the shortage is being felt by health care providers, schools, and parents. The Advisory Committee on Immunization Practices (ACIP), with concurrence from the AAFP and the Committee on Infectious Diseases of the AAP, has made several temporary changes in routine immunization recommendations. These changes prioritize limited vaccine supplies to the most critical doses in the schedule for the most vulnerable

children. However, this means that health care providers are sending children home without giving them all of their normally recommended vaccines. For example, the ACIP recommended that providers having supply problems with DTaP should defer vaccination of children aged 15--18 months with the fourth DTaP dose. If deferring the fourth dose does not leave enough DTaP to vaccinate infants, then the fifth DTaP dose (given to children aged 4--6 years) also should be deferred. Giving fewer than the usually recommended number of doses of PCV-7 vaccine to infants is another example of the revised recommendations. Sometimes, even when providers have been following the revised recommendations, they have still run out of vaccine. This puts children at risk, and puts a significant burden on providers to keep track of children they weren't able to immunize and recall them later.

School immunization requirements have also been affected, because supplies have not been adequate to assure that children in need of immunizations can get them. School requirements have been one of our most effective interventions to prevent outbreaks of vaccine-preventable diseases among school-aged children. School entry requirements for vaccines in shortage have been temporarily suspended in some states. A recent survey of state immunization programs found that 48% of states have made changes to their school entry requirements for Td, and about 10% have made changes to their school and daycare requirements for DTaP. When vaccine supply improves and the rules are reinstated, school staff will have to ensure that children missing required vaccines have received them. Finally, parents have experienced frustration and anxiety when they have made the effort to bring their child in for vaccinations, and have been told the child could not receive all the recommended vaccines during that visit.

While it is impossible to predict the larger public health impact of the current childhood vaccine shortages, there is clearly an increase in vulnerability to disease when children remain unvaccinated. CDC is carefully monitoring disease surveillance and immunization coverage data to assess the ongoing impact of the shortage. So far, there is no evidence of outbreaks related to the shortage.

CDC's Role in Maintaining the Supply of Childhood Vaccines

Vaccine Ordering and Distribution: CDC has contracts with all childhood vaccine manufacturers, through which states and other grantees purchase vaccine with public funds, including Vaccines for Children (VFC), Section 317 of the PHS Act, and state funds. A comparison of public childhood vaccine purchases with Biologic Surveillance Reports data on the total childhood vaccines distributed in the U.S. for calendar year 2000 shows that CDC's contracts accounted for 52% of the national childhood vaccine supply. To encourage multiple manufacturers to enter the market, contracts are sought for all licensed vaccines, with quantities purchased for each dependent on state and individual provider choice. CDC is monitoring state vaccine orders, in an effort to see

that the vaccines in shortage purchased through our contracts are distributed equitably. For example, CDC has restricted the number of doses states may order, based on the amount of vaccine they have in stock, and on the population in their state eligible for public vaccine.

ACIP Recommendations: CDC is working closely with the AAP, the AAFP, and the ACIP, which has recommended changes to the immunization schedule for each affected vaccine. These recommendations prioritize using available supply for the most vulnerable children, and include deferring booster doses and doses given later in the series. CDC has been working closely with state immunization programs and health care provider organizations to inform concerned parties about the recommended changes. Revisions to the schedule are described in detail on CDC's website (http://www.cdc.gov/nip).

Vaccine Stockpile: What is frequently referred to as the national vaccine stockpile is not, in actuality, a static, stand-alone warehouse of vaccine stored for emergency use. In order to ensure potency and safety, vaccine stockpiles must be continuously rotated and replenished. Therefore, CDC's approach has been to establish Storage and Rotation Contracts with manufacturers, frequently referred to as stockpiles. These contracts are essentially a mechanism for CDC to purchase vaccine over and above the national need from manufacturers, so that there is vaccine available to draw from in the event of an interruption in production.

The first "Storage and Rotation Contract" was initiated in 1983, when funding for the CDC stockpile was provided through Congressional appropriations to establish a 6-month strategic supply of each vaccine universally recommended at the time, including DTP, OPV, and MMR. Since 1983, stockpiles of vaccine have fluctuated according to funding appropriations, the immunization schedule, and whether there is a Federal contract for the vaccine. Two statutory authorities support CDC establishing and maintaining a six-month vaccine supply in stockpiles. They appear in the Vaccines for Children (VFC) Program statute and as a note to the National Childhood Vaccine Injury Act of 1986, as amended (NCVIA). Section 317 of the PHS Act (42 U.S.C. 247b) also provides authority to stockpile vaccines. Using VFC funds, CDC currently maintains stockpiles of three pediatric vaccines: MMR, e-IPV, and DT.

Stockpiles have been very effective in the past in alleviating brief disruptions in vaccine supply, and are an important resource to maintain. Between 1984 and 2002, CDC stockpiles were drawn on multiple times, when supplies of four different vaccines (OPV, DTP, E-IPV, and MMR) were interrupted. The interruptions were due to a variety of factors, and affected several manufacturers. Events precipitating the need to draw from the stockpile in the past have included fire damage at a vaccine production plant, production problems, such as disruptions in filling and packaging lines, and quality assurance difficulties. When such interruptions in production occurred, CDC and the manufacturers were able to fall back on

supplies of vaccine established through the Storage and Rotation Contracts, or stockpiles, to fill a temporary need. Usually, rather than distributing vaccine directly from the stockpile, CDC allows the manufacturer to borrow from it. Typically, vaccine taken out of the stockpile is replaced within a year.

Managing stockpiles effectively presents unique challenges. First, there is the issue of storage and maintaining continuous rotation of the stock. Maintaining excess inventory so that vaccine will be available for emergency use may be costly, not only in terms of vaccine, but also in terms of the facilities required for storage. Next, as new vaccines are developed, some old ones become obsolete; for example, oral polio vaccine has been replaced with inactivated polio vaccine, and whole cell DTP vaccine with the acellular pertussis DTaP vaccine. In order to minimize the financial risk of stockpiling vaccines that may not have a reliable future, the CDC approach in purchasing vaccines intended for a stockpile has been to prioritize vaccines that are routinely recommended, fully implemented, and have a single manufacturer. For example, MMR has consistently been included in the immunization schedule since its development, and has been stockpiled since 1983. Vaccines with multiple manufacturers, such as DTaP, Hepatitis B, and Hib vaccines, represent further complications in stockpile management. In such cases, the market share for each brand of the vaccine must be carefully evaluated to determine how much of each product should be stockpiled by each manufacturer. Storage and Rotation Contracts may need to be renegotiated if market share changes significantly among the companies. Finally, new vaccines pose unique challenges for stockpiling, as their demand is unclear and time is required to produce enough doses to be able to set aside an emergency supply.

Maintaining Communication with Manufacturers, the Public, and Health Care Providers:

The CDC is in constant communication with vaccine manufacturers regarding the status of vaccine production. CDC provides weekly vaccine supply updates on its website. This information is intended to help states and health care providers plan their immunization strategies, based on available vaccine supply. The website also provides links to state health departments, so parents and the public can find out more about local vaccine availability.

Options Under Consideration for Alleviating Current and Preventing Future Shortages

In addition to consulting with other DHHS agencies, such as FDA and Centers for Medicare & Medicaid Services (CMS), CDC is working with its partners in industry and with other groups to better understand the current shortages, identify potential short-term solutions, and prevent future shortages. What we learn from the current shortages should help us prevent or mitigate future shortages. Since the causes are multiple and complex, no single solution is likely to prevent future shortages. The partners we are

working with include the ACIP, the AAP, the AAFP, the Association of State and Territorial Health Officials (ASTHO), state immunization programs and vaccine manufacturers.

In addition to the input CDC is gathering from its partners, the National Vaccine Advisory Committee (NVAC) and the U.S. General Accounting Office (GAO) are conducting independent reviews of the situation. This past February, NVAC held a meeting with many of the stakeholders in vaccine supply including representatives of federal and state governments, vaccine manufacturers, and private providers. A report with recommendations for preventing future shortages is expected from NVAC later this summer, and DHHS is looking forward to reviewing it.

Early this year, GAO began working on a review requested by several legislators, designed to address factors relating to the current vaccine shortages. GAO is expected to release their report in late July.

Conclusion

The current childhood vaccine shortages are complex, unprecedented in scope and result from a number of factors. CDC has implemented a number of short-term measures to facilitate the efficient and effective use of available vaccine. CDC is also receiving input from a number of organizations regarding strategies to prevent such shortages in the future, and we look forward to hearing their recommendations.

Thank you for the opportunity to tell you about the current childhood vaccine shortages. At this time, I would be happy to answer your questions.

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